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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: CAPON *et al.*

Confirmation No.: 9120

Application No.: 09/875,082

Group Art Unit: 1636

Filed: June 5, 2001

Examiner: J. Ketter

For: COMPOSITIONS AND METHODS  
FOR DETERMINING ANTI-VIRAL  
DRUG SUSCEPTIBILITY AND  
RESISTANCE AND ANTI-VIRAL  
DRUG SCREENING

Attorney Docket No.: 11068-051-999

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application. This paper is being filed pursuant to C.F.R. § 1.34.

1. Enclosures accompanying this Information Disclosure Statement are:
  - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
  - 1b. A legible copy of :
    - ☒ Each U.S. patent application publication and U.S. and foreign patent;
    - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
    - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
    - ☐ all other information or portion which caused it to be listed on the PTO-1449.
  - 1c. ☒ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
  - 1d. ☒ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☐ Before the mailing of the first Office action on the merits;
- ☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114 (filed herewith).

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.

- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
  - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 503013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

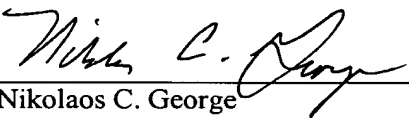
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

( Check Item 8a, 8b, or 8c)

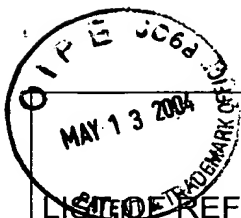
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 503013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: May 13, 2004

  
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**LISTED REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.  
11068-051-999

APPLICATION NO  
09/875,082

APPLICANT  
**Capon et al.**

FILING DATE  
June 5, 2001

GROUP  
1636

**U.S. PATENT DOCUMENTS**

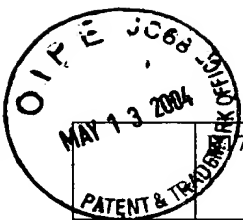
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	B01	5,874,565	2/1999	Rice et al.			
	B02	6,242,187	6/2001	Capon et al.			
	B03	20020034732	3/2002	Capon et al.			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B04	WO99/06597	2/1999	PCT				
	B05	International Search Report PCT/US2003/01379 1	4/2004	PCT				

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

B06	Blight et al., 2000, "Efficient Initiation of HCV RNA Replication in Cell Culture," <i>Science</i> 290:1972-1974
B07	Brown et al., 1994, "In Vitro Characterization of an Internal Ribosomal Entry Site (IRES) Present Within the 5' Nontranslated Region of Hepatitis A Virus RNA: Comparison with the IRES of Encephalomyocarditis Virus," <i>Journal of Virology</i> 68(2):1066-74.
B08	Chou et al., 1995, "Frequency of UL97 Phosphotransferase Mutations Related to Ganciclovir Resistance in Clinical Cytomegalovirus Isolates," <i>The Journal of Infectious Diseases</i> 172:239-242.
B09	Chung et al., 2001, "Hepatitis C Virus Replication is Directly Inhibited By IFN- $\alpha$ in a Full Length Binary Expression System," <i>Proc. Natl. Acad Sci USA</i> , 98(17):9847-9852.
B10	Enami, et al., 1991, "High-Efficiency Formation of Influenza Virus Transfectants" <i>Journal of Virology</i> 65(5):2711-13.
B11	Fuerst et al., 1986, "Eukaryotic Transient-Expression System Based on Recombinant Vaccinia Virus That Synthesizes Bacteriophage T7 RNA Polymerase" <i>Proc. Natl. Acad Sci USA</i> , 83:8122-26.
B12	Gerna et al., 1995, "Rapid Screening For Resistance to Ganciclovir and Foscarnet of Primary Isolates of Human Cytomegalovirus From Culture-Positive Blood Samples" <i>Journal of Microbiology</i> , 33(3):738-741.
B13	Glass et al., 1993, "Identification of the Hepatitis A Virus Internal Ribosome Entry Site: <i>In Vivo</i> and <i>In Vitro</i> Analysis of Bicistronic RNAs Containing the HAV 5' Noncoding Region" <i>Virology</i> , 193:842-852.
B14	Hahm et al., 1996, "Generation of a Novel Poliovirus with a Requirement of Hepatitis C Virus Protease NS3 Activity" <i>Virology</i> (1996) 226:318-326.
B15	Hirowatari et al., 1995, "A Novel Method for Analysis of Viral Proteinase Activity Encoded by Hepatitis C Virus in Cultured Cells," <i>Analytical Biochemistry</i> , 225:113-120.
B16	Houghton et al., 1996, "Hepatitis C Viruses" <i>Fields Virology 3<sup>rd</sup> Edition</i> Chapter 32: 1035-1058.



		Jang <i>et al.</i> , 1989, "Initiation of Protein Synthesis by Internal Entry of Ribosomes into the 5' Nontranslated Region of Encephalomyocarditis Virus RNA In Vivo," <i>Journal of Virology</i> , 63(4): 1651-1660.
	B18	Lawson <i>et al.</i> , 1995, "Recombinant Vesicular Stomatitis Viruses From DNA," <i>Proc Natl. Acad. Sci. USA</i> , 63: 4477-4481.
	B19	Lu <i>et al.</i> , 1996, "Poliovirus Chimeras Replicating Under the Translational Control of Genetic Elements of Hepatitis C Virus Reveal Unusual Properties of the Internal Ribosomal Entry Site of Hepatitis C Virus." <i>Proc Natl. Acad. Sci. USA</i> , 93: 1412-1417.
	B20	Mocarski, Edward S., 1996, "Cytomegaloviruses and Their Replication," <i>Fields Virology 3<sup>rd</sup> Edition Chapter 76</i> , 2447-22492.
	B21	Pelletier <i>et al.</i> , 1988, "Internal Initiation of Translation of Eukaryotic mRNA Directed by a Sequence Derived From Poliovirus RNA," <i>Nature</i> , 334: 320-325.
	B22	Rohll <i>et al.</i> , 1994, "The 5'-Untranslated Regions of Picornavirus RNAs Contain Independent Functional Domains Essential for RNA Replication and Translation," <i>Journal of Virology</i> , 68(7): 4384-91.
	B23	Schnell <i>et al.</i> , 1994, "Infectious Rabies Viruses From Cloned cDNA," <i>The EMBO Journal</i> , 13(18): 4195-4203.
	B24	Steinkuhler <i>et al.</i> , 1996, "Activity of Purified Hepatitis C Virus Protease NS3 on Peptide Substrates," <i>Journal of Virology</i> , 70(10): 6694-6700.
	B25	Tsukiyama-Kohara <i>et al.</i> , 1992, "Internal Ribosome Entry Site Within Hepatitis C Virus RNA," <i>Journal of Virology</i> , 66(3): 1476-1483.
	B26	Wang <i>et al.</i> , 1993, "Translation of Human Hepatitis C Virus RNA in Cultured Cells is Mediated by an Internal Ribosome-Binding Mechanism," <i>Journal of Virology</i> , 67(6): 3338-3344.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.